

## BIOSIGNAL INTENSITY MEASURING METHOD, BEDDING STATE JUDGING METHOD, AND BEDDING STATE MONITORING DEVICE

[0001] This application is the U.S. National Stage of PCT/JP2003/014087, filed November 5, 2003, which claims priority from Japanese Patent Application No. 2002-358712 filed November 7, 2002, the disclosures of both of which are incorporated herein in their entireties by reference thereto.

#### BACKGROUND

[0002] The disclosure relates in general to a biosignal intensity detecting method, a bedding state judging method, and a bedding state monitoring device. The methods and monitoring device are used to detect whether a target person is in or out of bed or bedclothes and whether the intensity level of biosignals from the person in bed is decreasing.

[0003] An elderly person, a person who requires care, or an inpatient is under the care of his or her family members, a nursing care worker, or a nurse in a hospital or a medical institution who must pay constant attention to the condition of their patient or elderly person but cannot be in attendance all the time.

[0004] For example, when a family lives with an elderly person who requires care, someone in the family must go to the elderly person's room frequently to check the condition or behavior of the elderly person. In a nursing-care institution or hospital, patrolling at night on a regular basis is required for checking the condition of a patient during nighttime. But under present circumstances it is difficult to find people to spare for patrolling. Additionally, in the case where an accident happens to a patient, there is no other way for the patient but to use a buzzer attached to a bed to contact hospital personnel. The buzzer is useless if the patient is in no condition to operate the buzzer. An elderly person living alone is at an even greater disadvantage. The elderly person has no attendants to take care of him or her, so others cannot know about his or her condition.

[0005] If an elderly person or patient in bed has an abnormality in his or her body and is left alone for a long time, he or she may be placed in a fatal condition. Hence a monitoring device, capable of constantly monitoring the condition and daily behavior of a patient, has been in great demand.

[0006] It is desirable to monitor the condition of a patient without imposing any mental or physical burden on the patient. For this reason, a device for noninvasive monitoring is imperative for monitoring the patient.

[0007] The inventor has proposed a novel method disclosed in Japanese Published Unexamined Patent Application No. H11-19056. According to the method, an air mat is laid under a subject and a minute differential pressure sensor for detecting the inner pressure of the mat is used to detect vibrations caused by the heartbeat of the subject in a noninvasive manner. The vibrations are processed as signals, which are detected as heartbeat signals or respiratory signals.

[0008] The inventor has also proposed an apparatus disclosed in Japanese Published Unexamined Patent Application No. 2002-58653. According to the apparatus, an air tube is laid under a subject and a minute differential pressure sensor for detecting the inner pressure of the air tube is used to detect vibrations caused by the heartbeat of the subject in a noninvasive manner. The vibrations are processed as signals, which are detected as heartbeat signals or respiratory signals.

[0009] In addition, a method for judging whether a person is in bed is disclosed in Japanese Published Unexamined Patent Application No. H5-192315. According to the method, an air mat is laid under the bed or bedclothes, and a pressure change of the air mat caused by the person's body motion, tossing, etc., is detected to make a judgment whether a person is in or out of bed.

[0010] The method disclosed in Japanese Published Unexamined Patent Application No. H5-192315 allows a monitoring person to know whether the subject is in or out of bed, but does not allow the monitoring person to know the condition or daily behavior of the subject.

#### SUMMARY

[0011] The inventor has disclosed in Japanese Published Unexamined Patent Application No. H11-19056 and Japanese Published Unexamined Patent Application No. 2002-58653, described above, methods for extracting heartbeat signals and respiratory signals, for use in the detection of microsignals. Detecting microsignals takes a great effort, and a temporary failure in detecting the signals may occur when an excessive large signal caused by the subject's tossing is generated. The methods, therefore, have a problem in terms of continuity in detection.

[0012] In order to solve the above mentioned problems, an object is to provide a biosignal detecting method, a bedding state judging method, and a bedding state monitor, which make it possible to detect the intensity of microsignals continuously and enable a judgment whether a subject is in or out of bed.

[0013] A first aspect is a biosignal measuring (detecting) method. Output signals from a noninvasive sensor, which detects biosignals from a lying subject, are amplified and attenuated with respect to noises other than the biosignals via a signal amplifying/shaping means. The biosignals are controlled by an automatic gain control (AGC) means to have sizes within a prescribed range, and parameters acquired by signal gains in a control circuit upon carrying out automatic gain control are output as the output signal intensity of the controlled signals to calculate biosignal intensity.

[0014] A second aspect is, in the biosignal measuring method, the signal amplifying/shaping means has an amplifying characteristic that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

[0015] A third aspect is, in the biosignal measuring method, the signal amplifying/shaping means has a band-pass filter that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

[0016] A fourth aspect is, in the biosignal measuring method, when the size of the output from the noninvasive sensor exceeds a prescribed range for more than a certain time, a judgment is made that a subject is making body motion.

[0017] A fifth aspect is a bedding state judging method. The output signals from the noninvasive sensor, which detects biosignals from a lying subject, are amplified and attenuated with respect to the noises other than the biosignals via the signal amplifying/shaping means. The amplified signals are controlled by the automatic gain control (AGC) means to have sizes within a prescribed range, and the parameters acquired by signal gains in the control circuit, upon carrying out automatic gain control, are calculated as the output signal intensity of the controlled signals. The calculated signal intensity is used to monitor the bedding state of the subject, such as a state of being in or out of bed, of weakening or stoppage of biosignals, of making body motion, or the like.

[0018] A sixth aspect is, in the bedding state judging method, the signal amplifying/shaping means has the amplifying characteristic that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

[0019] A seventh aspect is, in the bedding state judging method, the signal amplifying/shaping means has the band-pass filter that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

[0020] An eighth aspect of the invention is, in a bedding state monitor, which includes the noninvasive sensor that detects biosignals and the body motion of a lying subject, the signal amplifying/shaping means that attenuates the noises other than the biosignals included in the output signals from the noninvasive sensor, a non-bedding detecting sensor for confirming the subject's being out of bed, the automatic gain control means that controls signals given by eliminating noises from the output signals from the noninvasive sensor via the signal amplifying/shaping means so that the signals have sizes within a prescribed range, the signal intensity calculating means that calculates the parameters acquired by signal gains in the control circuit upon carrying out automatic gain control as the output signal intensity of the biosignals, and a bedding state judging means that makes a judgment on the subject's being in or out of bed, weakening or stoppage of biosignals, or the like, using a plurality of the signal intensities or parameters calculated from the signal intensities.

[0021] A ninth aspect is, in the bedding state monitor, the signal amplifying/shaping means has the amplifying characteristic that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

[0022] A tenth aspect is, in the bedding state monitor, the signal amplifying/shaping means has the band-pass filter that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

[0023] An eleventh aspect is, in the bedding state monitor, a body motion detecting means that detects body motion from the output of the noninvasive sensor, and the bedding state judging means monitors the occurrence of the body motion using output from the body motion detecting means.

[0024] A twelfth aspect is, in the bedding state monitor, the body motion detecting means judges that a subject is making body motion when the size of output from the noninvasive sensor exceeds a prescribed range for more than a certain time.

[0025] A thirteenth aspect is, in the bedding state monitor, the noninvasive sensor comprises a capacitor microphone for detecting micropressure, and a hollow, elastic tube or a hollow, elastic tube with an inserted core wire thinner than the hollowed part of the tube, the tube being connected to the microphone.

[0026] A fourteenth aspect is, in the bedding state monitor, the non-bedding detecting sensor is a sensor for detecting weight.

[0027] A fifteenth aspect is, in the bedding state monitor, the non-bedding detecting sensor is an infrared sensor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] The invention will be described with reference to the drawings, in which:

[0029] FIGS. 1A and 1B are block diagrams for depicting the flow of a procedure for detecting signals from a subject in a noninvasive manner and detecting biosignals using the detected signals;

[0030] FIG. 2 is a plan view of another embodiment of the non-bedding detecting sensor;

[0031] FIG. 3 is a block diagram depicting the details of the signal amplifying/shaping section;

[0032] FIG. 4 is a flowchart of a procedure for judging the presence or absence of biosignals;

[0033] FIG. 5 is a flowchart of a procedure for judging a subject's being in or out of bed;

[0034] FIG. 6 is an explanatory drawing for explaining a method for setting a gain in the AGC circuit; and

[0035] FIGS. 7A-7D are graphs showing biosignal output actually measured according to one embodiment.

DETAILED DESCRIPTION OF EMBODIMENTS

[0036] FIGS. 1A and 1B are the block diagrams depicting the flow of the procedure for detecting biosignals in a noninvasive manner, calculating the intensity of the biosignals, and making a judgment on the presence or absence of the biosignals and a bedding state, such as being in or out of bed, using the biosignal intensity output, according to an exemplary embodiment. FIG. 1B is a partial sectional view of FIG. 1A in the direction viewed from the arrow.

[0037] A noninvasive sensor 1 comprises a minute differential pressure sensor 1a and a pressure detecting tube 1b, and is arranged on a bed 8. As shown in FIGS. 1A and 1B, the pressure detecting tube 1b is folded back and forth several times to extend over a large portion of the bed to secure ample space for detecting pressure.

[0038] The pressure detecting tube 1b is placed on a hard sheet 9 spread on the bed 8, as shown in FIGS. 1A and 1B. The hard sheet 9 is covered with an elastic cushion sheet 10, which is further covered with bedclothes (a "futon" in Japanese, not shown in the drawings), on which a subject is laid. The pressure detecting tube 1b may be incorporated into the cushion sheet 10 to stabilize the position of the pressure detecting tube 1b.

[0039] The minute differential pressure sensor 1a detects the fluctuation of micropressure, and is of a capacitor microphone type for low frequency according to this exemplary embodiment. The minute differential pressure sensor 1a of this type, however, can be replaced with another type if the replaced type has a proper resolution and a dynamic range.

[0040] While an acoustic microphone, in general use, has a structure showing less sensitivity to a low-frequency region, the capacitor microphone for low frequency used for the embodiment is provided with a chamber formed behind a pressure-receiving surface, which improves the characteristics of the capacitor microphone for the low-frequency region. This makes the capacitor microphone applicable to the detection of the fluctuation of micropressure in the pressure detecting tube 1b. The capacitor microphone is also superior in measuring minute differential pressure, having a resolution of 0.2 Pa (pascal) and a dynamic range of approximately 50 Pa to exert a capability several times as high as a conventional minute differential pressure sensor using ceramics. The capacitor microphone, therefore, is suitable for detecting micropressure applied to the pressure detecting tube 1b via biosignals transmitted through the body surface of a subject. The frequency characteristics of the capacitor microphone are almost flat in a range from 0.1 Hz to 30 Hz (hertz), which is another factor for making the capacitor microphone appropriate to the detection of minute biosignals, such as heart rate, breathing rate, pulse, very small body movements or the like.

[0041] The pressure detecting tube 1b, which functions as a pressure detecting section in the noninvasive sensor 1, must have proper elasticity so that the inner pressure of the pressure detecting tube 1b changes in response to the fluctuation range of pressure caused by the biosignals. Also, the capacity of a hollowed part in the tube 1b should be selected properly so that a pressure change inside the tube 1b is transmitted to the minute differential pressure sensor 1a at a proper response speed. When the pressure detecting tube 1b cannot have the proper elasticity and hollowed part capacity simultaneously, a core wire of proper thickness may be inserted into the hollowed part and extended along the entire length of the tube 1b to secure the proper capacity of the hollowed part. Inserting the core wire of the proper thickness into the pressure detecting tube 1b also prevents such trouble that the tube 1b is completely crushed and becomes unable to transmit the pressure change to the minute differential pressure sensor 1a.

[0042] A non-bedding detecting sensor 11 is a sensor for helping to see if a subject is out of a bed 8. FIG. 1A shows, as an example of the sensor 11, that a tape switch is stretched

across the whole length of the bed 8. The tape switch is turned on when the subject's body is on the switch, and turned off when the body is removed.

[0043] FIG. 2 is an example where an infrared sensor is used as the non-bedding detecting sensor 11. The infrared sensor comprises an emitting part 11a and a light-receiving part 11b, and they are in an arrangement where infrared rays emitted from the emitting part 11a are received by the light-receiving part 11b. The infrared sensor is switched on when the subject lies on the bed and switched off when the subject is out of the bed.

[0044] FIG. 3 is the block diagram that depicts the details of a signal amplifying/shaping section 2, which has a function of amplifying signals output from the noninvasive sensor 1 while attenuating noises other than biosignals included in the output signals. As shown in FIG. 3, the signal amplifying/shaping section 2 comprises a signal amplifying circuit 21 and a band-pass filter 22. The signal amplifying circuit 21 amplifies output signals from the noninvasive sensor 1 and the band-pass filter 22 passes only the signals that have frequencies required for measuring the intensity of biosignals out of the output signals. According to this exemplary embodiment, the band-pass filter 22 is given a preset filtering function that passes signals having frequencies ranging from approximately 7 Hz to 30 Hz and attenuates the signals in the frequency bandwidth other than 7 Hz to 30 Hz.

[0045] Signals caused by the subject include heartbeat signals, pulse signals, respiratory signals, and signals generated by body motions, such as tossing. The heartbeat signals appear in a frequency bandwidth of 10 Hz to 20 Hz, while the pulse signals in a frequency bandwidth of 0.8 Hz to 1.5 Hz, and the respiratory signals in a frequency bandwidth of 0.2 Hz to 0.4 Hz. Meanwhile, noises, which are not caused by the subject, include noises due to wind, which appear as signals having frequencies of around 1 Hz, noises due to emissions from a fluorescent lamp, appearing as signals of 50 Hz to 60 Hz, low-frequency noises due to voices, appearing as signals of more than 300 Hz, and low-frequency noises from a construction site or factory, appearing as signals of 20 Hz to 300 Hz.

[0046] When the passing band of the signal amplifying/shaping section 2 is set within the range of 7 Hz to 30 Hz as in the exemplary embodiment, most of noises not caused by the subject can be attenuated, and the passed heartbeat signals and pulse signals are sent to an automatic gain control section 3. Although the respiratory signals are cut off, the presence or absence of biosignals can be confirmed without the respiratory signals, as the respiratory signals are sometimes discontinued when a non-breathing time occurs, so that the above passing band setting presents no trouble in measuring the intensity of biosignals.

[0047] The band-pass filter 22 can be eliminated from the signal amplifying/shaping section 2 when the signal amplifying circuit 21 is given the characteristics that amplify signals in the main frequency band of biosignals and attenuates signals in the frequency band of noises. It is also applicable that the signal amplifying circuit 21 is set to pass signals in the main frequency band and the band-pass filter 22 is provided to further attenuate noise elements.

[0048] The automatic gain control section 3 is composed of an automatic gain control (AGC) circuit, through which the gain of output from the signal amplifying/shaping section 2 is automatically controlled so that the output is processed into signals within a prescribed level. The gain resulting from the gain control is sent to a signal intensity calculating section 4. In this exemplary embodiment, the gain of output signals is set so that the amplitude of the signals is reduced when the peak of the signals surpasses an upper limit threshold while being increased when the peak drops below a lower limit threshold, as shown in FIG. 6. Respective output signals processed into the prescribed level are sent to a bedding state judgment control section 6.

[0049] The signal intensity calculating section 4 calculates the intensity of the signals, using the gain resulting from the gain control on the output from the noninvasive sensor 1 and the environmental noise sensor 2 at the automatic gain control section 3.

[0050] Because the gain given by the AGC circuit is small when the signals are large and is large when the signals are small, a function that represents signal intensity in inverse proportion to the gain is required in order to represent signal intensity using the gain.

[0051] On the other hand, when output from the noninvasive sensor 1 repeatedly surpasses the upper limit of the automatic gain control in a prescribed time, it is assumed that the subject's body is in motion, such as tossing or turning. A body motion detecting/calculating section 5 monitors such a time, during which output from the noninvasive sensor 1 surpasses the upper limit, and detects the body motion.

[0052] The bedding state judgment control section 6 is a judgment section that makes a judgment on the presence or absence of biosignals and the subject's being in or out of bed on the basis of output from the signal intensity calculating section 4, the body motion detecting/calculating section 5, and the non-bedding detecting sensor 11.

[0053] Next, a method for measuring the biosignal intensity and for making judgments on the presence or absence of biosignals and the subject's being in or out of bed are described.

[0054] According to the exemplary embodiment, biosignals are detected by detecting a pressure change in the pressure detecting tube 1b arranged under the lying subject. Because of this, vibrations not caused by the subject and transmitted to bedclothes, such as vibrations caused by wind or voices, steps of people other than the subject in a room, by traffic, construction, or factory operation, etc., may also be applied to the pressure detecting tube 1b as additional signals, which makes it impossible to detect the accurate intensity of biosignals.

[0055] Thus, according to the method for measuring biosignal intensity the above problem is solved by attenuating signals caused by vibrations other than the subject, which are included in output signals from the noninvasive sensor 1 for detecting biosignals, at the signal amplifying/shaping section 2 and calculating the accurate intensity of biosignals at the biosignal intensity calculating section 4. The signal amplifying/shaping section 2 is set to attenuate signals in a bandwidth other than that ranging from 7 Hz to 30 Hz. A bandwidth set for attenuation, however, is not limited to the above bandwidth, and its range may be changed if the intensity of biosignals can be measured after all.

[0056] A biosignal intensity F is calculated at the biosignal intensity calculating section 4 using the following equation (A):

$$F = Aa - Aa_0 \quad (A)$$

where  $Aa$  is the transfer average of the intensity of signals from the noninvasive sensor 1 in a certain time, while  $Aa_0$  is that of the intensity of signals from the noninvasive sensor 1 in a second when no load is applied on the noninvasive sensor 1.  $Aa_0$  is measured at initial setting and the absence of the subject to use the latest value. The value of the biosignal intensity F is a maximum at F (100), and F (50) indicates 50% intensity of F (100).

[0057] FIG. 4 is the flowchart of an example of the procedure for judging the presence or absence of biosignals at the bedding state judgment control section 7. At the start of the procedure, 'biosignal is absent' is set. When data of  $Aa$  and  $Aa_0$  are taken in, the biosignal intensity F is calculated using the equation (A). When the biosignal intensity F exceeds F (30), a judgment of 'biosignal is present' is given. When the biosignal intensity F is F (30) or lower, a judgment of 'biosignal is absent' is given.

[0058] When the biosignal intensity F exceeds F (30) to produce the judgment of 'biosignal is present,' the data of  $Aa$  and  $Aa_0$  are taken in again and the calculation using the equation (A) is repeated. If the calculation gives the biosignal intensity F of F (20) or lower, the judgment of 'biosignal is absent' is given, and the same steps are repeated.

[0059] Thus, the value F (30) is used as a threshold for the biosignal intensity F in judging the presence or absence of biosignals. This threshold, however, may be changed according to differences in age, physical structure, or condition among individual subjects.

[0060] FIG. 5 is a flowchart of an example of the procedure for judging a subject's moving from in bed to out of bed or being in or out of bed, and/or the presence or absence of biosignals. In other words, the procedure is used to monitor the subject to see if he or she is on the bed or leaving the bed, or to see if on the bed, any accident, such as the stoppage of biosignals, is occurring.

[0061] At the start of the procedure, 'out of bed' is set. When data of  $A_a$  and  $A_{a0}$  are taken in, the biosignal intensity F is calculated using the equation (A). When the tape switch used as the non-bedding detecting sensor 11 is on and the biosignal intensity F is above F (30), it is confirmed that the subject is in the bed 8 and biosignals are detected, therefore, the judgment of 'in bed' is given.

[0062] When the presence of the subject in the bed is confirmed, the data of  $A_a$  and  $A_{a0}$  are taken in again and the calculation by the equation (A) is repeated.

[0063] If the calculation gives the biosignal intensity F of F (20) or lower, output from the non-bedding detecting sensor 11 is checked. When the output from the non-bedding detecting sensor 11 is not observed, it indicates that a given weight is not applied to the bed, which leads to a judgment that the subject is out of the bed. At this time, the procedure returns to the start of the flowchart. On the other hand, when the output from the non-bedding detecting sensor 11 is observed, it indicates that the biosignal intensity F is at a low level of F (20) or lower despite the fact that the subject is in the bed. This leads to a judgment of 'biosignal stoppage', that is, the abnormal state of the subject, at which an alarm is emitted from an alarm device 12 to report the abnormal state to the prescribed personnel, institution, or post.

[0064] FIGs. 7A-7D are graphs showing the biosignal output actually measured according to the biosignal intensity measuring method and the bedding state judging method. FIG. 7A shows the waveform of the AGC output of a noninvasive sensor signal.

[0065] FIG. 7B is a graph showing the signal intensity  $A_a$  given by calculating the intensity of signals from the noninvasive sensor 1 at the signal intensity calculating section 4, where the signal intensity  $A_a$  is normalized to have a maximum value of 1. FIG. 7C is a graph showing a signal from which the biosignal intensity  $A_{a0}$  under a non-loaded condition is deducted.

[0066] FIG. 7D represents a signal output for judging the presence or absence of biosignals, which is a result of a judgment made in accordance to the flowchart shown in FIG. 4. If the signal output reaches 1, it is judged that biosignals are present. The signal output shown in FIG. 7D is combined with output from the non-bedding detecting sensor 11 for judgment about a subject's being in or out of bed and for monitoring of the abnormal state of the subject according to the flowchart shown in FIG. 5.

[0067] The method and apparatuses according to the described embodiments enable noninvasive monitoring of a subject's being in or out of bed, of the biosignal intensity, and of the presence or absence of body motion, such as tossing or turning. This makes it possible to detect the abnormal state of the subject, such as the stoppage of biosignals, and also to know the daily behavior of the subject, including a pattern of tossing or turning, getting in or out of bed, etc., by recording information of the subject constantly. As a result, checking the overall life pattern of the subject becomes possible. Such detected or checked information may be transmitted to subject's close relatives or family doctor in a remote location to help the receiver maintain the subject's health.

[0068] Also, according to the biosignal intensity measuring method, by using the noninvasive sensor as a detecting unit for detecting biosignals from the subject, the subject is freed from any physical burden in daily activity during the monitoring operation, so that the noninvasive sensor can be used without any concern. Additionally, the method includes a unit that reduces environmental noises not caused by the subject, which realizes accurate measuring of biosignal intensity.

[0069] Furthermore, the bedding state judging method and the bedding state judging apparatus, which includes the use of the biosignal intensity measuring method, enable the confirmation of a subject's being in or out of bed and monitoring of the subject to detect any abnormal state and thereby inform a medical professional or subject's family members of the abnormality.

[0070] If the subject is an elderly person, his or her family members do not have to visit the subject frequently to see if he or she is all right because the family members are assured that they are informed of any abnormality immediately upon occurrence. Further, the family members are provided with information of the subject's being in or out of bed as well. In a case of an elderly person living alone, monitoring information of the elderly person can be transmitted to a remote place using the method and apparatus as described, which makes remote monitoring of the person possible.

[0071] The method and apparatus are also applicable to institutions like hospitals or homes for the elderly, reducing the burden on nurses and the labor to patrol the bed areas.

[0072] As described above, the biosignal intensity measuring method, bedding state judging method, and bedding state monitor are useful, for example, in medical institutions, institutions for the elderly, hospices, and homes and are also good for use as a monitoring system and condition detecting system for the elderly.

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#### DESCRIPTION

#### BIOSIGNAL INTENSITY MEASURING METHOD, BEDDING STATE JUDGING METHOD, AND BEDDING STATE MONITORING DEVICE

##### Technical Field

This invention relates in general to a biosignal intensity detecting method, a bedding state judging method, and a bedding state monitoring device. The methods and monitoring device are used to detect whether a target person is in or out of bed or bedclothes and whether the intensity level of biosignals from the person in bed is decreasing.

##### Background Art

An elderly person, a person who requires care, or an inpatient is under the care of his or her family members, a nursing care worker, or a nurse in a hospital or medical institution who must pay constant attention to the condition of their patient or elderly person but cannot be in attendance all the time.

For example, when a family lives with an elderly person who requires care, someone in the family must go to the elderly person's room frequently to check the condition or behavior of the elderly person. In a nursing-care institution or hospital, patrolling at night on a regular basis is required for checking the condition of a patient during nighttime. But under present circumstances it is difficult to find hands to spare for patrolling. Additionally, in the case that an accident happens to a patient, there is no other way for the patient but to use a buzzer attached to a bed to contact hospital personnel, and the buzzer is useless if the patient is in no condition to be able to operate the buzzer. An elderly person living alone is at an even greater disadvantage. The elderly person has no attendants to take care of him or her, so others cannot know about his or her condition.

If an elderly person or patient in bed has an abnormality in his or her body and is left alone for a long time, he or she may be placed in a fatal condition. Hence a monitoring device, capable of constantly monitoring the condition and daily behavior of a patient, has been in great demand.

It is desirable to monitor the condition of a patient without imposing any mental or physical burden on the patient. For this reason, a device for noninvasive monitoring is imperative in

monitoring the patient.

The inventor has proposed a novel method disclosed in Japanese Published Unexamined Patent Application No. H11-19056. According to the method, an air mat laid under a subject and a minute differential pressure sensor for detecting the inner pressure of the mat are used to detect vibrations caused by the heartbeat of the subject in a noninvasive manner. The vibrations are processed as signals, which are detected as heartbeat signals or respiratory signals.

The inventor has also proposed an apparatus disclosed in Japanese Published Unexamined Patent Application No. 2002-58653. According to the apparatus, an air tube laid under a subject and a minute differential pressure sensor for detecting the inner pressure of the air tube are used to detect vibrations caused by the heartbeat of the subject in a noninvasive manner. The vibrations are processed as signals, which are detected as heartbeat signals or respiratory signals.

In addition, a method for judging whether or not a person is in bed is disclosed in Japanese Published Unexamined Patent Application No. H5-192315. According to the method, an air mat is laid under the bed or bedclothes, and a pressure change of the air mat caused by the person's body motion, tossing, etc., is detected to make a judgment on whether a person is in or out of bed.

The method disclosed in Japanese Published Unexamined Patent Application No. H5-192315 allows a monitoring person to know whether the subject is in or out of bed, but does not allow to know the condition or daily behavior of the subject.

The inventor's proposal has disclosed in Japanese Published Unexamined Patent Application No. H11-19056 and Japanese Published Unexamined Patent Application No. 2002-58653, methods for extracting heartbeat signals and respiratory signals, for use in the detection of microsignals. Detecting microsignals takes a great effort, and a temporary failure in detecting the signals may occur when an excessive large signal caused by the subject's tossing is generated. The methods, therefore, have a problem in terms of continuity in detection.

In order to solve the above mentioned problems, an object of the present invention is to provide a biosignal detecting method, a bedding state judging method, and a bedding state monitor, which make it possible to detect the intensity of microsignals continuously and enable a judgment on whether a subject is in or

out of bed.

#### Disclosure of the Invention

A first aspect of the invention is the biosignal measuring (detecting) method. Output signals from a noninvasive sensor, which detects biosignals from a lying subject, are amplified and attenuated with respect to noises other than the biosignals via a signal amplifying/shaping means. The biosignals are controlled by an automatic gain control (AGC) means to have sizes within a prescribed range, and parameters acquired by signal gains in a control circuit upon carrying out automatic gain control are output as the output signal intensity of the controlled signals to calculate biosignal intensity.

A second aspect of the invention is the biosignal measuring method according to the first aspect of the invention. The signal amplifying/shaping means has an amplifying characteristic that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

A third aspect of the invention is the biosignal measuring method according to the first aspect of the invention. The signal amplifying/shaping means has a band-pass filter that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

A fourth aspect of the invention is the biosignal measuring method according to the first aspect of the invention. When the size of the output from the noninvasive sensor exceeds a prescribed range for more than a certain time, a judgment is made that a subject is making body motion.

A fifth aspect of the invention is the bedding state monitoring method. The output signals from the noninvasive sensor, which detects biosignals from a lying subject, are amplified and attenuated with respect to the noises other than the biosignals via the signal amplifying/shaping means. The amplified signals are controlled by the automatic gain control (AGC) means to have sizes within a prescribed range, and the parameters acquired by signal gains in the control circuit upon carrying out automatic gain control are calculated as the output signal intensity of the controlled signals. The calculated signal intensity is used to monitor the bedding state of the subject, such as a state of being in or out of bed, of weakening or stoppage of biosignals, of making body motion, or the like.

A sixth aspect of the invention is the bedding state monitoring method according to the fifth aspect of the invention. The signal amplifying/shaping means has the amplifying characteristic that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

A seventh aspect of the invention is the bedding state monitoring method according to the fifth aspect of the invention. The signal amplifying/shaping means has the band-pass filter that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

An eighth aspect of the invention is the bedding state monitor, which includes the noninvasive sensor that detects biosignals and the body motion of a lying subject, the signal amplifying/shaping means that attenuates the noises other than the biosignals included in the output signals from the noninvasive sensor, a non-bedding detecting sensor for confirming the subject's being out of bed, the automatic gain control means that controls signals given by eliminating environmental noises from the output signals from the noninvasive sensor via an environmental filter so that the signals have sizes within a prescribed range, the signal intensity calculating means that calculates the parameters acquired by signal gains in the control circuit upon carrying out automatic gain control as the output signal intensity of the biosignals, and a bedding state judging means that makes a judgment on the subject's being in or out of bed, weakening or stoppage of biosignals, or the like, using a plurality of the signal intensities or parameters calculated from the signal intensities.

A ninth aspect of the invention is the bedding state monitor according to the eighth aspect of the invention. The signal amplifying/shaping means has the amplifying characteristic that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

A tenth aspect of the invention is the bedding state monitor according to the eighth aspect of the invention. The signal amplifying/shaping means has the band-pass filter that reduces the signal level of heartbeat signals and pulse signals in a bandwidth other than the main bandwidth of the signals.

An eleventh aspect of the invention is the bedding state monitor according to the eighth aspect of the invention. Furthermore, the eleventh aspect of the invention has a body motion

detecting means that detects body motion from the output of the noninvasive sensor, and the bedding state judging means that monitors the occurrence of the body motion using output from the body motion detecting means.

A twelfth aspect of the invention is the bedding state monitor according to the eleventh aspect of the invention. The body motion detecting means judges that a subject is making body motion when the size of output from the noninvasive sensor exceeds a prescribed range for more than a certain time.

A thirteenth aspect of the invention is the bedding state monitor according to the eighth aspect of the invention. The noninvasive sensor consists of a capacitor microphone for detecting micropressure, and a hollow, elastic tube or a hollow, elastic tube with an inserted core wire thinner than the hollowed part of the tube, the tube being connected to the microphone.

A fourteenth aspect of the invention is the bedding state monitor according to the eighth aspect of the invention. The non-bedding detecting sensor is a sensor for detecting weight.

A fifteenth aspect of the invention is the bedding state monitor according to the eighth aspect of the invention. The non-bedding detecting sensor is an infrared sensor.

#### Brief Description of the Drawings

FIGS. 1 are block diagrams for depicting the flow of a procedure for detecting signals from a subject in a noninvasive manner and detecting biosignals using the detected signals, according to an embodiment of the present invention;

FIG. 2 is a plane view of another embodiment of the non-bedding detecting sensor;

FIG. 3 is a block diagram for depicting the details of the signal amplifying/shaping section;

FIG. 4 is a flowchart of a procedure for judging the presence or absence of biosignals;

FIG. 5 is a flowchart of a procedure for judging a subject's being in or out of bed;

FIG. 6 is an explanatory drawing for explaining a method for setting a gain in the AGC circuit; and

FIGS. 7 are graphs showing biosignal output actually measured according to an embodiment of the present invention.

#### Best Mode for Carrying Out the Invention

A detailed description of the embodiments of the present invention is given with reference to the drawings.

FIGS. 1 are the block diagrams for depicting the flow of the procedure for detecting biosignals in a noninvasive manner, calculating the intensity of the biosignals, and making a judgment on the presence or absence of the biosignals and a bedding state, such as being in or out of bed, using the biosignal intensity output, according to an embodiment of the present invention. FIG. 1B is a partial sectional view of FIG. 1A in the direction viewed from the arrow.

A noninvasive sensor 1 comprises a minute differential pressure sensor 1a and a pressure detecting tube 1b, and is arranged on a bed 8. As shown in FIGS. 1, the pressure detecting tube 1b is folded back several times and is extended widely around the bed to secure an ample space for detecting pressure.

The pressure detecting tube 1b is placed on a hard sheet 9 spread on the bed 8, as shown in FIGS. 1. The hard sheet 9 is covered with an elastic cushion sheet 10, which is further covered with bedclothes (not shown in the drawings), such as a futon, on which a subject is laid. The pressure detecting tube 1b may be incorporated into the cushion sheet 10 to stabilize the position of the pressure detecting tube 1b.

The minute differential pressure sensor 1a detects the fluctuation of micropressure, and is of a capacitor microphone type for low frequency according to this embodiment. The minute differential pressure sensor 1a of this type, however, can be replaced with another type if the replaced type has a proper resolution and a dynamic range.

While an acoustic microphone in general use has a structure showing less sensitivity to a low-frequency region, the capacitor microphone for low frequency used for the embodiment is provided with a chamber formed behind a pressure-receiving surface, which improves the characteristics of the capacitor microphone for the low-frequency region, making the capacitor microphone applicable to the detection of the fluctuation of micropressure in the pressure detecting tube 1b. The capacitor microphone is also superior in measuring minute differential pressure, having a resolution of 0.2 Pa (pascal) and a dynamic range of approximately 50 Pa to exert a capability several times as high as a conventional minute differential pressure sensor utilizing ceramics. The capacitor microphone, therefore, is suitable for detecting micropressure

applied to the pressure detecting tube 1b via biosignals transmitted through the body surface of a subject. The frequency characteristics of the capacitor microphone are almost flat in a range from 0.1 Hz to 30 Hz (hertz), which is another factor for making the capacitor microphone appropriate to the detection of minute biosignals, such as a heart rate, a breathing rate, or the like.

The pressure detecting tube 1b, which functions as a pressure detecting section in the noninvasive sensor 1, must have proper elasticity so that the inner pressure of the pressure detecting tube 1b changes in response to the fluctuation range of pressure caused by biosignals. Also, the capacity of a hollowed part in the tube 1b should be selected properly so that a pressure change inside the tube 1b is transmitted to the minute differential pressure sensor 1a at a proper response speed. When the pressure detecting tube 1b cannot have the proper elasticity and hollowed part capacity simultaneously, a core wire of proper thickness may be inserted into the hollowed part and extended along the whole length of the tube 1b to secure the proper capacity of the hollowed part. Inserting the core wire of the proper thickness into the pressure detecting tube 1b also prevents such trouble that the tube 1b is completely crushed to become unable to transmit the pressure change to the minute differential pressure sensor 1a.

A non-bedding detecting sensor 11 is a sensor for helping to see if a subject is out of a bed 8 or not. FIG. 1A shows an example of the sensor 11 that a tape switch is stretched across the whole length of the bed 8. The tape switch is turned on when the subject's body is placed on the switch, while turned off when the body is removed.

FIG. 2 is an example that an infrared sensor is used as the non-bedding detecting sensor 11. The infrared sensor comprises an emitting part 11a and a light-receiving part 11b, and they are in an arrangement where infrared rays emitted from the emitting part 11a are received by the light-receiving part 11b. The infrared sensor is switched on when the subject lies on the bed, while switched off when the subject is out of the bed.

FIG. 3 is the block diagram for depicting the details of a signal amplifying/shaping section 2, which has a function of amplifying signals output from the noninvasive sensor 1 while attenuating noises other than biosignals included in the output signals. As shown in FIG. 3, the signal amplifying/shaping section

2 comprises a signal amplifying circuit 21 and a band-pass filter 22. The signal amplifying circuit 21 amplifies output signals from the noninvasive sensor 1 and the band-pass filter 22 passes only the signals that have frequencies required for measuring the intensity of biosignals out of the output signals. According to this embodiment, the band-pass filter 22 is given a preset filtering function that passes signals having frequencies ranging from approximately 7 Hz to 30 Hz and attenuates the signals in the frequency bandwidth other than 7 Hz to 30 Hz.

Signals caused by the subject include heartbeat signals, pulse signals, respiratory signals, and signals generated by body motions, such as tossing. The heartbeat signals appear in a frequency bandwidth of 10 Hz to 20 Hz, while the pulse signals in a frequency bandwidth of 0.8 Hz to 1.5 Hz, and the respiratory signals in a frequency bandwidth of 0.2 Hz to 0.4 Hz. Meanwhile, noises, which are not caused by the subject, include noises due to wind, which appear as signals having frequencies of around 1 Hz, noises due to emission from a fluorescent lamp, appearing as signals of 50 Hz to 60 Hz, low-frequency noises due to voices, appearing as signals of more than 300 Hz, and low-frequency noises from a construction site or factory, appearing as signals of 20 Hz to 300 Hz.

When the passing band of the signal amplifying/shaping section 2 is set within the range of 7 Hz to 30 Hz as the embodiment, most of noises not caused by the subject can be attenuated, and passed heartbeat signals and pulse signals are sent to an automatic gain control section 3. Although the respiratory signals are cut off, the presence or absence of biosignals can be confirmed without the respiratory signals, since the respiratory signals are sometimes discontinued when a non-breathing time occurs, so that the above passing band setting presents no trouble in measuring the intensity of biosignals.

The band-pass filter 22 can be eliminated from the signal amplifying/shaping section 2 when the signal amplifying circuit 21 is given the characteristics that amplify signals in the main frequency band of biosignals and attenuates signals in the frequency band of noises. It is also applicable that the signal amplifying circuit 21 is set to pass signals in the main frequency band and the band-pass filter 22 is provided to further attenuate noise elements.

The automatic gain control section 3 is composed of an

automatic gain control (AGC) circuit, through which the gain of output from the signal amplifying/shaping section 2 is automatically controlled so that the output is processed into signals within a prescribed level. The gain resulted from the gain control is sent to a signal intensity calculating section 4. In this embodiment, the gain of output signals is set so that the amplitude of the signals is reduced when the peak of the signals surpasses an upper limit threshold while being increased when the peak drops below a lower limit threshold, as shown in FIG. 6. Respective output signals processed into the prescribed level are sent to a bedding state judgment control section 6.

The signal intensity calculating section 4 calculates the intensity of the signals, using the gain resulting from the gain control on the output from the noninvasive sensor 1 and the environmental noise sensor 2 at the automatic gain control section 3.

Since the gain given by the AGC circuit is small when the signals are large and is large when the signals are small, a function that represents signal intensity in inverse proportion to the gain is required in order to represent signal intensity using the gain.

On the other hand, when output from the noninvasive sensor 1 repeatedly surpasses the upper limit of the automatic gain control in a prescribed time, it is assumed that the subject made body motion, such as tossing. A body motion detecting/calculating section 5 monitors such a time, during which output from the noninvasive sensor 1 surpasses the upper limit, and detects the body motion.

The bedding state judgment control section 6 is a judgment section that makes a judgment on the presence or absence of biosignals and the subject's being in or out of bed on the basis of output from the signal intensity calculating section 4, the body motion detecting/calculating section 5, and the non-bedding detecting sensor 11.

Next, a method for measuring the biosignal intensity and for making judgment on the presence or absence of biosignals and the subject's being in or out of bed are described.

According to the embodiment of the present invention, biosignals are detected by detecting a pressure change in the pressure detecting tube 1b arranged under the lying subject. Because of this, vibrations not caused by the subject and transmitted to bedclothes, such as vibrations caused by wind or voices/steps of people other than the subject in a room, by traffic,

construction, or factory operation, etc., may also be applied to the pressure detecting tube 1b as additional signals, which makes it impossible to detect the accurate intensity of biosignals.

Then, according to the method for measuring biosignal intensity in the present invention, the above problem is solved by attenuating signals caused by vibrations other than the subject, which are included in output signals from the noninvasive sensor 1 for detecting biosignals, at the signal amplifying/shaping section 2 and calculating the accurate intensity of biosignals at the biosignal intensity calculating section 4. The signal amplifying/shaping section 2 is set to attenuate signals in a bandwidth other than that ranging from 7 Hz to 30 Hz. A bandwidth set for attenuation, however, is not limited to the above bandwidth, and its range may be changed if the intensity of biosignals can be measured after all.

A biosignal intensity  $F$  is calculated at the biosignal intensity calculating section 4 using the following equation (A);

$$F = Aa - Aa_0 \quad (A)$$

where  $Aa$  is the transfer average of the intensity of signals from the noninvasive sensor 1 in a certain time, while  $Aa_0$  is that of the intensity of signals from the noninvasive sensor 1 in a second when no load is applied on the noninvasive sensor 1.  $Aa_0$  is measured at initial setting and the absence of the subject to use the latest value. The value of the biosignal intensity  $F$  is maximum at  $F(100)$ , and  $F(50)$  indicates 50% intensity of  $F(100)$ .

FIG. 4 is the flowchart of an example of the procedure for judging the presence or absence of biosignals at the bedding state judgment control section 7. At the start of the procedure, 'biosignal is absent' is set. When data of  $Aa$  and  $Aa_0$  are taken in, the biosignal intensity  $F$  is calculated using the equation (A). When the biosignal intensity  $F$  exceeds  $F(30)$ , a judgment of 'biosignal is present' is given. When the biosignal intensity  $F$  is  $F(30)$  or lower, 'biosignal is absent' is given.

When the biosignal intensity  $F$  exceeds  $F(30)$  to bring the judgment of 'biosignal is present,' the data of  $Aa$  and  $Aa_0$  are taken in again and the calculation by the equation (A) is repeated. If the calculation gives the biosignal intensity  $F$  of  $F(20)$  or lower, the judgment of 'biosignal is absent' is given, and then the same steps are repeated.

Thus, the value  $F(30)$  is used as a threshold for the biosignal intensity  $F$  in judging the presence or absence of biosignals. This

threshold, however, may be changed according to difference in age, physical structure, or condition among individual subjects.

FIG. 5 is a flowchart of an example of the procedure for judging a subject's moving from in bed to out of bed or being in or out of bed, and/or the presence or absence of biosignals. In other words, the procedure is used to monitor the subject to see if he or she is on the bed or leaving the bed, or to see if on the bed, any accident such as the stoppage of biosignals, is occurring or not.

At the start of the procedure, 'out of bed' is set. When data of  $A_a$  and  $A_{a0}$  are taken in, the biosignal intensity  $F$  is calculated using the equation (A). When the tape switch used as the non-bedding detecting sensor 11 is on and the biosignal intensity  $F$  is above  $F (30)$ , it is confirmed that the subject is in the bed 8 and biosignals are detected, therefore, the judgment of 'in bed' is given.

When the presence of the subject in the bed is confirmed, the data of  $A_a$  and  $A_{a0}$  are taken in again and the calculation by the equation (A) is repeated.

If the calculation gives the biosignal intensity  $F$  of  $F (20)$  or lower, output from the non-bedding detecting sensor 11 is checked. When the output from the non-bedding detecting sensor 11 is not observed, it indicates that a given weight is not applied to the bed, which leads to a judgment that the subject is out of the bed. At this time, the procedure returns to the start of the flowchart. On the other hand, when the output from the non-bedding detecting sensor 11 is observed, it indicates that the biosignal intensity  $F$  is at a low level of  $F (20)$  or lower despite the fact that the subject is in the bed. This leads to a judgment of 'biosignal stoppage', that is, the abnormal state of the subject, at which an alarm is emitted from an alarm device 12 to report the abnormal state to the prescribed personnel, institution, or post.

FIG. 7 is the graph showing the biosignal output actually measured according to the biosignal intensity measuring method and the bedding state judging method. FIG. 7A shows the waveform of the AGC output of a noninvasive sensor signal.

FIG. 7B is a graph showing the signal intensity  $A_a$  given by calculating the intensity of signals from the noninvasive sensor 1 at the signal intensity calculating section 4, where the signal intensity  $A_a$  is normalized to have a maximum value of 1. FIG. 7C is a graph showing a signal from which the biosignal intensity  $A_{a0}$ ,

under a non-loaded condition is deducted.

FIG. 7D represents a signal output for judging the presence or absence of biosignals, which is a result of a judgment made in accordance to the flowchart shown in FIG. 4. If the signal output reaches 1, it is judged that biosignals are present. The signal output shown in FIG. 7D is combined with output from the non-bedding detecting sensor 11 for judgment on a subject's being in or out of bed and for monitoring of the abnormal state of the subject according to the flowchart shown in FIG. 5.

The method and apparatuses according to the embodiments of the present invention enable noninvasive monitoring of a subject's being in or out of bed, of the biosignal intensity, and of the presence or absence of body motion, such as tossing. This makes it possible to detect the abnormal state of the subject, such as the stoppage of biosignals, and also to know the daily behavior of the subject, including a pattern of tossing, getting in or out of bed, etc., by recording information of the subject constantly, thus checking the overall life pattern of the subject becomes possible. Such detected or checked information may be transmitted to subject's close relatives or family doctor in a remote place to help them maintain subject's health.

Also, according to the biosignal intensity measuring method of the present invention, by using the noninvasive sensor as a detecting unit for detecting biosignals from the subject, the subject is made free from the physical burden in daily activity during the monitoring operation, so that the noninvasive sensor can be used without any concern. Additionally, the method includes a unit that reduces environmental noises not caused by the subject, which realizes accurate measuring of biosignal intensity.

Furthermore, the bedding state judging method and the bedding state judging apparatus, which includes the use of the biosignal intensity measuring method, enable the confirmation of a subject's being in or out of bed and monitoring of the subject to detect any abnormal state and inform a nurse or subject's family members of the abnormality.

If the subject is an elderly person, his or her family members do not have to visit the subject frequently to see if he or she is all right because the family members are ensured that any abnormality is informed immediately upon occurring, and the family members are provided with information of the subject's being in or out of bed as well. In a case of an elderly person living alone,

monitoring information of the elderly person can be transmitted to a remote place using the method and apparatus of the present invention, which makes remote monitoring of the person possible.

The invention is also applicable to institutions like hospitals or homes for the elderly, reducing the burden on nurses and the labor in patrolling.

#### Industrial Applicability

As described above, the biosignal intensity measuring method, bedding state judging method, and bedding state monitor, according to the invention, are useful in medical institutions, institutions for the elderly, etc., and also good for use as a monitoring system and condition detecting system for the elderly.